

# DADE

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**DADE INTERNATIONAL**

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MicroScan Inc  
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## 510(k) Submission Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Sharolyn Lontsch, Sr. Regulatory Affairs Administrator
Fax:	916-374-3144
Date prepared:	May 28, 1996
Product Name:	Microbiological Identification System
Trade Name:	MicroScan® Rapid Gram-Negative Identification Type 3 Panel
Intended Use:	Rapid identification of non-fastidious aerobic and facultatively anaerobic gram-negative bacilli from human clinical specimens
510(k) Notification:	Modified Device Request
Predicate devices:	MicroScan® Rapid Gram-Negative Identification Type 2 Panel API 20E System

## 510(k) Summary:

The proposed MicroScan® Rapid Gram-Negative Identification Panel (referred to as the MicroScan RNID Type 3 panel) is substantially equivalent in intended use, technology, and methodology to the current MicroScan® Rapid Gram-Negative Identification Type 2 Panel and is substantially equivalent to the API 20E System with regard to performance.

The Premarket Notification (510[k]) presents data in support of a formulation modification for the current MicroScan® Rapid Gram-Negative Identification Type 2 Panel and requests a release to market for the modified device (i.e., the MicroScan® Rapid Gram-Negative Identification Type 3 Panel).

Efficacy testing was conducted with a total of 405 fresh and stock gram-negative isolates at two (2) external sites. MicroScan® Rapid Gram-Negative Identification Type 3 Panel identifications were compared with API 20E System identifications. Isolates meeting a pre-defined criteria were either repeated and/or were arbitrated using conventional tube methodologies. Overall the MicroScan RNID Type 3 panel demonstrated a combined final agreement (percent agreement at the species level, high and low probabilities) of 97.1% (393/405) when compared with API 20E System identifications supplemented with conventional tube methodologies. There was only one (1) Very Rare Biotype (VRB) result.

Reproducibility testing with the MicroScan® Rapid Gram-Negative Identification Type 3 Panel (RNID) was comprised of 15 stock isolates tested at two (2) external sites and at MicroScan. Reproducibility was evaluated using individual biochemical test results, biotype frequencies, and overall identification performance. Overall the MicroScan RNID Type 3 panel gave results which were > 95% in agreement with expected results.

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MicroScan® Rapid Gram-Negative Identification Type 3 Panel

Quality control (QC) testing with the MicroScan® Rapid Gram-Negative Identification Type 3 Panel (RNID) was conducted with eight (8) strains and a saline blank. Quality control (QC) testing was performed on the API 20E System at the clinical trial sites according to the API 20E procedure manual. The QC performance was acceptable for both systems during the clinical trial. The four (4) strains recommended for routine user (customer) QC for the MicroScan RNID Type 3 panel provide adequate coverage to verify that the panel is performing as expected during routine use (e.g., > 95% agreement). User QC recommendations fulfill the requirements for user QC as described by NCCLS Document M7-A3 (*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically*, Ed.3; Approved Standard. Pennsylvania, NCCLS, December 1993).

We therefore believe that the MicroScan® Rapid Gram-Negative Identification Type 3 Panel (RNID) gives appropriate rapid identifications with non-fastidious aerobic and facultatively anaerobic gram-negative bacilli from human clinical specimens.